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### Geriatric Subjects

In GL1, GL2, and GL3, there were 8 subjects aged 65 and older who were randomized to DYSPORT™ 50 Units in 5 equal aliquots of 10 Units (4) or placebo (4). None of the geriatric DYSPORT™ subjects were a treatment success at maximum frown at Day 30.

### **16 HOW SUPPLIED/STORAGE AND HANDLING**

DYSPORT™ for Injection is supplied in a sterile, single-use, 3 mL glass vial. DYSPORT™ must be stored under refrigeration at 2–8°C (36–46°F). Protect from light.

Administer DYSPORT™ within 4 hours of reconstitution; during this period reconstituted DYSPORT™ should be stored under refrigeration at 2–8°C (36–46°F). Do not freeze after reconstitution.

Do not use after the expiration date on the vial. All vials, including expired vials, or equipment used with DYSPORT™ should be disposed of carefully as is done with all medical waste.

#### Cervical Dystonia

Each vial contains 500 Units of freeze-dried abobotulinumtoxinA.

Box containing 1 vial—NDC 15054-0500-1

Box containing 2 vials—NDC 15054-0500-2

#### Glabellar Lines

Each vial contains 300 Units of freeze-dried abobotulinumtoxinA.

Box containing 1 vial—NDC 99207-500-30

DYSPORT™ contains a unique hologram on the vial label and carton. If you do not see the hologram, do not use the product. Instead contact 877-397-7671 between 7:00 a.m. and 5:00 p.m. Mountain Standard Time, Monday through Friday.

### **17 PATIENT COUNSELING INFORMATION**

The physician should provide a copy of the FDA-Approved Patient Medication Guide and review the contents with the patient. Patients should be advised to inform their doctor or pharmacist if they develop any unusual symptoms (including difficulty with swallowing, speaking or breathing), or if any known symptom persists or worsens.

Patients should be counseled that if loss of strength, muscle weakness, blurred vision or drooping eyelids occur, they should avoid driving a car or engaging in other potentially hazardous activities.

Manufactured by:

Ipsen Biopharm Ltd.

Wrexham, LL13 9UF, UK

Distributed by:

Tercica, Inc.

a subsidiary of the Ipsen Group

Brisbane, CA 94005

and

Medicis Aesthetics Inc.

a wholly owned subsidiary of Medicis Pharmaceutical Corporation

Scottsdale, AZ 85256

### **MEDICATION GUIDE**

**DYSPORT™ (DIS-port)**

**(abobotulinumtoxinA)**

#### **Injection**

Read the Medication Guide that comes with DYSPORT™ before you start using it and each time DYSPORT™ is given to you. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment. You should share this information with your family members and caregivers.

**What is the most important information I should know about DYSPORT™?**

**DYSPORT™ may cause serious side effects that can be life threatening. Call your doctor or get medical help right away if you have any of these problems after treatment with DYSPORT™:**

- **Problems swallowing, speaking, or breathing.** These problems can happen hours to weeks after an injection of DYSPORT™ usually because the muscles that you use to breathe and swallow can become weak after the injection. Death can happen as a complication if you have severe problems with swallowing or breathing after treatment with DYSPORT™.

- People with certain breathing problems may need to use muscles in their neck to help them breathe. These patients may be at greater risk for serious breathing problems with DYSPO<sup>TM</sup>.
- Swallowing problems may last for several weeks. People who can not swallow well may need a feeding tube to receive food and water. If swallowing problems are severe, food or liquids may go into your lungs. People who already have swallowing or breathing problems before receiving DYSPO<sup>TM</sup> have the highest risk of getting these problems.
- **Spread of toxin effects.** In some cases, the effect of botulinum toxin may affect areas of the body away from the injection site and cause symptoms of a serious condition called botulism. The symptoms of botulism include:
  - loss of strength and muscle weakness all over the body
  - double vision
  - blurred vision and drooping eyelids
  - hoarseness or change or loss of voice (dysphonia)
  - trouble saying words clearly (dysarthria)
  - loss of bladder control
  - trouble breathing
  - trouble swallowing

These symptoms can happen hours to weeks after you receive an injection of DYSPO<sup>TM</sup>. These problems could make it unsafe for you to drive a car or do other dangerous activities. See "What should I avoid while receiving DYSPO<sup>TM</sup>?"

#### **What is DYSPO<sup>TM</sup>?**

DYSPO<sup>TM</sup> is a prescription medicine that is injected into muscles and used:

- to treat the abnormal head position and neck pain that happens with cervical dystonia (CD) in adults
- to improve the look of moderate to severe frown lines between the eyebrows (glabellar lines) in adults younger than 65 years of age for a short period of time (temporary)

CD is caused by muscle spasms in the neck. These spasms cause abnormal position of the head and often neck pain. After DYSPO<sup>TM</sup> is injected into muscles, those muscles are weakened for up to 12 to 16 weeks or longer. This may help lessen your symptoms.

Frown lines (wrinkles) happen because the muscles that control facial expression are used often (muscle tightening over and over). After DYSPO<sup>TM</sup> is injected into the muscles that control facial expression, the medicine stops the tightening of these muscles for up to 4 months.

It is not known whether DYSPO<sup>TM</sup> is safe or effective in children under 18 years of age.

It is not known whether DYSPO<sup>TM</sup> is safe or effective for the treatment of other types of muscle spasms. It is not known whether DYSPO<sup>TM</sup> is safe or effective for the treatment of other wrinkles.

#### **Who should not take DYSPO<sup>TM</sup>?**

##### **Do not take DYSPO<sup>TM</sup> if you:**

- are allergic to DYSPO<sup>TM</sup> or any of the ingredients in DYSPO<sup>TM</sup>. See the end of this Medication Guide for a list of ingredients in DYSPO<sup>TM</sup>
- are allergic to cow's milk protein
- had an allergic reaction to any other botulinum toxin product such as Myobloc<sup>® 1</sup> or Botox<sup>® 1</sup>
- have a skin infection at the planned injection site

#### **What should I tell my doctor before taking DYSPO<sup>TM</sup>?**

##### **Tell your doctor about all your medical conditions, including if you have:**

- a disease that affects your muscles and nerves (such as amyotrophic lateral sclerosis [ALS or Lou Gehrig's disease], myasthenia gravis or Lambert-Eaton syndrome). See "What is the most important information I should know about DYSPO<sup>TM</sup>?"
- allergies to any botulinum toxin product
- had any side effect from any botulinum toxin product in the past
- a breathing problem, such as asthma or emphysema
- swallowing problems
- bleeding problems

- diabetes
- a slow heart beat or other problem with your heart rate or rhythm
- plans to have surgery
- had surgery on your face
- weakness of your forehead muscles (such as trouble raising your eyebrows)
- drooping eyelids
- any other change in the way your face normally looks

**Tell your doctor if you:**

- are pregnant or plan to become pregnant. It is not known if DYSPORT™ can harm your unborn baby
- are breast-feeding or planning to breast-feed. It is not known if DYSPORT™ passes into breast milk

**Tell your doctor about all the medicines you take**, including prescription and nonprescription medicines, vitamins and herbal and other natural products. Using DYSPORT™ with certain other medicines may cause serious side effects. **Do not start any new medicines while taking DYSPORT™ without talking to your doctor first.**

**Especially tell your doctor if you:**

- have received any other botulinum toxin product in the last four months
- have received injections of botulinum toxin, such as Myobloc® (Botulinum Toxin Type B)<sup>1</sup> or Botox® (Botulinum Toxin Type A)<sup>1</sup> in the past; be sure your doctor knows exactly which product you received
- have recently received an antibiotic by injection
- take muscle relaxants
- take an allergy or cold medicine
- take a sleep medicine

**Ask your doctor if you are not sure if your medicine is one that is listed above.**

Know the medicines you take. Keep a list of your medicines with you to show your doctor and pharmacist each time you get a new medicine.

**How should I take DYSPORT™?**

- DYSPORT™ is an injection that your doctor will give you
- DYSPORT™ is injected into the affected muscles
- Your doctor may give you another dose of DYSPORT™ after 12 weeks or longer, if it is needed
- If you are being treated for CD, your doctor may change your dose of DYSPORT,™ until you and your doctor find the best dose for you
- The dose of DYSPORT™ is not the same as the dose of any other botulinum toxin product

**What should I avoid while taking DYSPORT™?**

DYSPORT™ may cause loss of strength or general muscle weakness, blurred vision, or drooping eyelids within hours to weeks of taking DYSPORT.™ **If this happens, do not drive a car, operate machinery, or do other dangerous activities. See "What is the most important information I should know about DYSPORT™?"**

**What are the possible side effects of DYSPORT™?**

**DYSPORT™ can cause serious side effects. See "What is the most important information I should know about DYSPORT™?"**

**Other side effects of DYSPORT™ include:**

- dry mouth
- injection site discomfort or pain

- tiredness
- headache
- neck pain
- muscle pain
- eye problems: double vision, blurred vision, decreased eyesight, problems with focusing the eyes (accommodation), drooping eyelids, swelling of the eyelids
- allergic reactions. Symptoms of an allergic reaction to DYSPORT™ may include: itching, rash, red itchy welts, wheezing, asthma symptoms, or dizziness or feeling faint. Tell your doctor or get medical help right away if you get wheezing or asthma symptoms, or if you get dizzy or faint

**Tell your doctor if you have any side effect that bothers you or that does not go away. These are not all the possible side effects of DYSPORT.™ For more information, ask your doctor or pharmacist.**

**Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.**

**General information about DYSPORT™:**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide.

This Medication Guide summarizes the most important information about DYSPORT.™ If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about DYSPORT™ that is written for healthcare professionals. For more information about DYSPORT™ call 877-397-7671 or go to [www.dysport.com](http://www.dysport.com) or [www.DysportUSA.com](http://www.DysportUSA.com).

**What are the ingredients in DYSPORT™?**

Active ingredient: (botulinum toxin Type A)

Inactive ingredients: human albumin, and lactose. DYSPORT™ may contain cow's milk protein.

Issued May 2009

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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and

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Scottsdale, AZ 85256

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**PRINCIPAL DISPLAY PANEL - 300 Units Sample Vial**

Distributed by: Medicis Aesthetics Inc.

Scottsdale, AZ 85256, USA

Manufactured by: Ipsen Biopharm Ltd.

Wrexham, LL13 9UF, UK

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See enclosed prescribing information

for dosage and dilution information.

Dilution Date/Time:

abobotulinumtoxinA

**Dysport™**

for Injection

For intramuscular use

**300 UNITS/VIAL**

NDC 99207-500-01

**Rx Only**

U.S. Lic. 1787

Part No. 1602018301

Professional Sample—Not For Sale

Lot:

Exp.: